Complete Summary

GUIDELINE TITLE

Management of HIV in pregnancy.

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). Management of HIV in pregnancy. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2004 Apr. 12 p. (Guideline; no. 39). [49 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Human immunodeficiency virus (HIV) infection in pregnancy

Note: This guideline relates to the management of HIV in pregnancy in developed countries, as it was considered beyond the scope of a single guideline to address management in both developed and developing country settings.

GUIDELINE CATEGORY

Management
Prevention
Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Obstetrics and Gynecology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations for physicians on the use of antiretroviral drugs and elective cesarean delivery in human immunodeficiency virus (HIV)-infected pregnant women to reduce HIV transmission from mother to child

TARGET POPULATION

Human immunodeficiency virus (HIV)-infected pregnant women and their newborn infants

INTERVENTIONS AND PRACTICES CONSIDERED

Screening, Evaluation, Counselling, and General Management

1. Screening for human immunodeficiency virus (HIV) early in pregnancy
2. Screening for genital and other infections (in HIV positive pregnant women)
    - *Chlamydia trachomatis*
    - *Neisseria gonorrhoeae*
    - Bacterial vaginosis
    - Syphilis
    - Hepatitis B
    - Hepatitis C
3. Ultrasound scanning
4. Screening for Down syndrome and fetal anomalies
5. Monitoring of plasma viral load
6. Reporting of all women with HIV during pregnancy to the National Study of HIV in Pregnancy and Childhood (NSHPC)
7. Patient management by interdisciplinary team
8. Patient counselling
9. Disclosure of patient HIV status
10. Patient education and discussion of treatment plan
11. Consultation with a HIV specialist

Treatment/Management (to Reduce the Risk of HIV Transmission)

1. Anti-retroviral therapy antenatally and intrapartum to the mother and to the neonate
    - Highly active anti-retroviral therapy (HAART)

    - Short-term anti-retroviral therapy (START)
    - Single agent zidovudine
2. Delivery by elective caesarean section
3. Prophylactic antibiotics (in women undergoing caesarean section)
4. Management of women undergoing vaginal delivery
5. Avoidance of breastfeeding
6. Antiretroviral treatment of infants born to HIV-positive women
7. Prepregnancy management of couples discordant for HIV who wish to conceive

MAJOR OUTCOMES CONSIDERED

- Incidence of human immunodeficiency virus (HIV) in pregnant women
- Mother to child transmission rate of human immunodeficiency virus (HIV)
- Maternal morbidity and mortality
- Maternal plasma viral load
- Adverse effects of antiretroviral therapy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A literature search was performed using Medline (1983-2002). The keywords used were "HIV," "pregnancy," "mother-to-child transmission," and "vertical transmission." Reference lists of the articles identified were hand searched for additional articles. Articles relating to management of HIV in pregnancy in developing country settings were excluded.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well-designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The recommendations were graded according to the level of evidence upon which they were based. The grading scheme used was based on a scheme formulated by the Clinical Outcomes Group of the National Health Service (NHS) Executive.

Grade A - Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia, Ib)

Grade B - Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendations (evidence levels IIa, IIb, III)

Grade C - Requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (evidence level IV)

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Following discussion in the Guidelines and Audit Committee, each green-top guideline is formally peer reviewed. At the same time the draft guideline is published on the Royal College of Obstetricians and Gynaecologists (RCOG) website for further peer discussion before final publication.

The names of author(s) and nominated peer reviewers are included in the original guideline document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.

Levels of evidence (**Ia-IV**) and grading of recommendations (**A-C**) are defined at the end of the "Major Recommendations" field.

Antenatal Care

A - Pregnant women should be offered screening for human immunodeficiency virus (HIV) early in pregnancy because appropriate antenatal interventions can reduce maternal-to-child transmission of HIV infection.

All midwives should have sufficient understanding of HIV and prevention of mother-to-child transmission to enable them to include HIV antibody testing among the routine booking investigations. However, a positive HIV antibody test result should be given to the woman in person by an appropriately trained health professional; this may be a specialist nurse, midwife, HIV physician, or obstetrician.

C - Women diagnosed as HIV positive during pregnancy should be managed by a multidisciplinary team.

There should be a clear referral pathway for pregnant women who are HIV positive. This should include an HIV physician, an obstetrician, a midwife, a paediatrician, and may also include a psychiatric team and support groups. [Evidence level IV]

Women with particular social difficulties, such as those with housing or immigration problems, will require considerable input from social workers. Women who use drugs will require additional support from drug dependency specialists. A carefully documented detailed plan of care and multidisciplinary meetings are important aspects of the antenatal care of the woman who is HIV positive, whether she is diagnosed before or during pregnancy, and training in giving this information. Counselling should encompass the full implications of an HIV-positive diagnosis during pregnancy, which must be addressed over several visits.

It is important that all health professionals involved in the antenatal and intrapartum care of a woman who is HIV positive are aware of her HIV diagnosis and plan of care, and this should be explained to the woman. However, she should be reassured that her confidentiality will be respected. The issue of disclosure of the HIV diagnosis to her partner should be handled with sensitivity. Detailed guidance has been published by the General Medical Council. The woman's HIV diagnosis may be disclosed to a known sexual contact, in order to protect him from acquiring infection, where the woman has not informed him and cannot be persuaded to do so. The woman must be told of the disclosure and the clinician must be prepared to justify it. Information must not be disclosed to others, for example relatives, who are not at risk of infection. Health professionals should not assume that the woman's partner or family members are aware of her HIV diagnosis, even though they may attend antenatal visits and be present at the delivery. Care should be taken to avoid inadvertent disclosure in such situations.

A - Women diagnosed HIV positive during pregnancy should be informed that interventions (such as antiretroviral therapy, caesarean section, and avoidance of breastfeeding) can reduce the risk of mother-to child HIV transmission from 25-30% to less than 2%.

Interventions to reduce the risk of HIV transmission should be discussed:

- Anti-retroviral therapy, given antenatally and intrapartum to the mother and to the neonate for the first 4-6 weeks of life
- Delivery by elective caesarean section
- Avoidance of breastfeeding

[Evidence level Ib]

Plasma viral load and CD4 T-lymphocyte measurements should be reviewed by the HIV physicians at regular intervals during pregnancy. They will advise as to the choice and timing of anti-retroviral therapy and the need for prophylaxis of *Pneumocystis carinii* pneumonia (PCP). PCP prophylaxis is usually administered when the CD4 T-lymphocyte count is below 200 x 10^6/L. The first line treatment is cotrimoxazole (a folate antagonist). Women taking anti-retroviral drugs should be monitored for drug toxicities (full blood count, urea and electrolytes, liver function tests, lactate and blood glucose) and should have a detailed ultrasound scan to detect fetal anomalies potentially attributable to teratogenesis.

C - All women with HIV during pregnancy (whether diagnosed before or during pregnancy) should be reported to the National Study of HIV in Pregnancy and Childhood at the Royal College of Obstetricians and Gynaecologists (RCOG).

Clinicians in the UK should report prospectively all women with HIV during pregnancy to the National Study of HIV in Pregnancy and Childhood (NSHPC), which complies with the Data Protection Act. Completed forms should be sent to the NSHPC at the RCOG. [Evidence level IV]

C - All pregnant women who are HIV positive should be screened for genital infections during pregnancy. This should be done as early as possible in pregnancy and repeated at around 28 weeks. Any infection detected should be treated according to UK national guidelines.

In view of the biological plausibility that increased HIV replication in the genital tract secondary to local infection could increase the risk of mother-to-child HIV transmission, it is recommended that all pregnant women are screened for genital infections. This should include tests for *Chlamydia trachomatis, Neisseria gonorrhoeae*, and bacterial vaginosis. Screening for syphilis, hepatitis B, and hepatitis C should also be performed if this has not already been performed at booking.

C - Screening for Down syndrome and fetal anomalies should be offered. A detailed ultrasound scan for fetal anomalies is important after first-trimester exposure to highly active anti-retroviral therapy (HAART) and folate antagonists used for prophylaxis against PCP.

C - The risks of mother-to-child transmission with chorionic villus sampling or second-trimester amniocentesis are uncertain. Where invasive prenatal diagnosis is contemplated, the advice of the fetal medicine specialist and HIV physician should be sought and prophylaxis with HAART considered.

There are few data on the risks of iatrogenic mother-to-child HIV transmission occurring as a result of chorionic villus sampling or amniocentesis. However, where such a procedure is performed and the pregnant woman is not already taking HAART, the HIV physician may advise that HAART be given prophylactically prior to the procedure to reduce transmission risk [Evidence level IV].

C - Presentation with symptoms or signs of pre-eclampsia, cholestasis, or other signs of liver dysfunction during pregnancy may indicate drug toxicity, and early liaison with HIV physicians should be sought.

Recommendations for Prescribing Anti-Retroviral Therapy in Pregnancy

A - All women who are HIV positive should be advised to take anti-retroviral therapy during pregnancy and at delivery.

A - Women who do NOT require HIV treatment for their own health require anti-retroviral therapy to prevent mother-to-child transmission. Anti-retroviral therapy is usually commenced between 28 and 32 weeks of gestation and should be continued intrapartum. A maternal sample for plasma viral load should be taken at delivery. Anti-retroviral therapy is usually discontinued soon after delivery but the precise time of discontinuation should be discussed with the HIV physician. Zidovudine is usually administered orally to the neonate for four to six weeks.

One option is the use of a simplified single-agent zidovudine regimen, given orally twice daily antenatally, intravenously intrapartum, and discontinued immediately after delivery. It is recommended that all women receiving a single-agent zidovudine regimen should be delivered by elective caesarean section. [Evidence level Ib]

An alternative option is a short-term anti-retroviral therapy (START) regimen, where HAART is taken for the duration of the pregnancy and discontinued shortly after delivery, provided that the maternal viral load is undetectable. For this reason it is important that a maternal blood sample for viral load is taken at the time of delivery. The precise time at which START is discontinued should be discussed with the HIV physician. [Evidence level IV]

A - Women with advanced HIV should be treated with a HAART regimen. The start of treatment should be deferred until after the first trimester, if possible, and should be continued after delivery.

Initiation of HAART should be deferred until after the first trimester if possible. Resistance testing may be performed. Many HIV physicians advise that unless zidovudine resistance is detected, this drug should be incorporated into the HAART regimen, as it is the anti-retroviral drug for which the most extensive safety data are available regarding use in pregnancy. The maternal regimen should be continued after delivery and care should be taken to ensure that doses are not missed around the time of delivery. [Evidence level IV]

A - Women who conceive while taking HAART should continue their HAART regimen if it is effectively suppressing plasma viraemia. For women whose regimen is not suppressing viraemia, a change in therapy after the first trimester may be indicated.

If the HAART regimen being used is effectively suppressing viraemia, this should be continued, both to improve maternal morbidity and mortality and to reduce transmission. [Evidence level Ia]

For women whose HAART regimen is not suppressing their viraemia, resistance-testing should be undertaken, and a change in therapy after the first trimester may be indicated. [Evidence level IV]

Women who present with HIV late in pregnancy or during labour, such that a formal immunological and virological assessment is not possible, should be treated with HAART, to include zidovudine. Zidovudine should be administered intravenously intrapartum and the HAART regimen should be continued intrapartum and postpartum until the results of the CD4 lymphocyte count and plasma viral load are known. [Evidence level IV]

For these women, a HAART regimen including zidovudine should be used. Zidovudine should be administered intravenously intrapartum and the HAART regimen should be continued intrapartum and postpartum until the results of the CD4 count and viral load are available. These women should be delivered by caesarean section. Consideration should be given to the timing of caesarean section to allow peak concentrations in the fetal circulation.

All women who receive anti-retroviral therapy in pregnancy should be registered prospectively with the Anti-retroviral Pregnancy Registry, which in Europe is managed by GlaxoSmithKline.

Mode of Delivery

A - Women who are HIV positive who have a detectable plasma viral load and/or who are NOT taking HAART should be offered a planned caesarean section as it reduces the risk of mother-to-child transmission of HIV.

C - Further research is needed to evaluate the effect on mother-to-child transmission and maternal health of planned caesarean section for women who are taking HAART or who have very low viral loads.

It is recommended that delivery by elective caesarean section should be timed to take place after 38 weeks of gestation.

All women who are HIV-positive undergoing caesarean section should receive prophylactic antibiotics. [Evidence level III]

Some women will prefer to avoid caesarean section and the views of the mother and her obstetric history are important factors. Long labours, particularly those with prolonged ruptured membranes and those ending in emergency caesarean section, should be avoided. Multiparous women who have delivered vaginally before may be particularly favourable candidates for vaginal delivery. Women who are planning to return to a country where subsequent caesarean section deliveries may not be possible or safe may have a particularly strong preference for vaginal delivery. [Evidence level IIb]

C - Women who opt for a planned vaginal delivery should have their membranes left intact for as long as possible. Use of fetal scalp electrodes and fetal blood sampling should be avoided. Women should continue their HAART regimen throughout labour and if an intravenous infusion of zidovudine is required it should be commenced at the onset of labour and continued until the umbilical cord has been clamped. A maternal sample for plasma viral load should be taken at delivery. The cord should be clamped as early as possible after delivery and the baby should be bathed immediately after the birth. [Evidence level III/IV]

Women taking HAART, who have an undetectable plasma viral load, should continue their usual oral HAART regimen throughout labour. In addition, intravenous zidovudine infusion during labour may be recommended by the HIV physician in certain circumstances, for example, for a woman who chooses to deliver vaginally despite a detectable plasma viral load. If a zidovudine infusion is required, it should be started at the onset of labour and should be continued until the umbilical cord has been clamped. [Evidence level Ib]

Electronic fetal monitoring should be performed according to guidelines from the National Institute for Health and Clinical Excellence (NICE). HIV infection per se is not an indication for continuous electronic fetal monitoring. The membranes should be left intact for as long as possible. Fetal scalp electrodes and fetal blood sampling should be avoided. An emergency caesarean section should be

performed for the usual obstetric reasons and to avoid a prolonged labour and prolonged rupture of membranes. [Evidence level IV]

If there is preterm rupture of membranes, with or without labour, the risk of HIV transmission should be set against the risk of preterm delivery. [Evidence level IIa]

Postpartum Management for the Mother

A - In the UK all women who are HIV positive should be advised not to breastfeed their babies.

Management of the Neonate

A - All infants born to women who are HIV positive should be treated with anti-retroviral therapy from birth.

Infants of mothers who received zidovudine antenatally and intrapartum, either as single-agent therapy or as part of a HAART regimen, should be given single-agent oral zidovudine.

HAART for neonates may be considered in the case of mothers who started anti-retroviral therapy late in pregnancy. [Evidence level IV]

Definitions:

Grading of Recommendations

Grade A - Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia, Ib)

Grade B - Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendations (evidence levels IIa, IIb, III)

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Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

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III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendations (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of human immunodeficiency virus (HIV)-infected pregnant women and reduction in the incidence of mother-to-child HIV transmission

POTENTIAL HARMS

- Possible side effects of antiretroviral therapy including increased risk of congenital abnormalities, gastrointestinal disturbances, hepatotoxicity, rashes, glucose intolerance, diabetes, and mild self-limiting anaemia.
- Delivery by caesarean section is associated with anaesthetic, intraoperative, and postoperative complications.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Clinical guidelines are: "systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions." Each guideline is systematically developed using a standardised methodology. Exact details of this process can be found in Clinical Governance Advice No. 1: *Guidance for the Development of Royal College of Obstetricians & Gynaecologists (RCOG) Green-top Guidelines*.
- These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution

and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). Management of HIV in pregnancy. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2004 Apr. 12 p. (Guideline; no. 39). [49 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Apr

GUIDELINE DEVELOPER(S)

Royal College of Obstetricians and Gynaecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

Royal College of Obstetricians and Gynaecologists

GUIDELINE COMMITTEE

Guidelines and Audit Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Professor Deirdre J Murphy, MRCOG (Chair); Lizzy Dijeh (Secretary); Ms Toni Belfield, Consumers' Representative; Professor P R Braude, FRCOG, Chairman, Scientific Advisory Committee; Mrs C Dhillon, Head of Clinical Governance and Standards Dept.; Dr Martin Dougherty, A. Director NCC-WCH; Miss L M M Duley, FRCOG, Chairman, Patient Information Subgroup; Mr Alan S Evans, FRCOG; Dr Mehmet R Gazvani, MRCOG; Dr Rhona G Hughes, FRCOG; Mr Anthony J Kelly MRCOG; Dr Gwyneth Lewis, FRCOG, Department of Health; Dr Mary A C Macintosh, MRCOG, CEMACH; Dr Tahir A Mahmood, FRCOG; Mrs Caroline E Overton, MRCOG, Reproductive medicine; Dr David Parkin, FRCOG; Oncology; Ms Wendy Riches, NICE; Mr Mark C Slack, MRCOG, Urogynaecology; Mr Stephen A Walkinshaw, FRCOG, Maternal and Fetal Medicine; Dr Eleni Mavrides, Trainees Representative

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Guideline authors are required to complete a "declaration of interests" form.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.

Print copies: Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Bookshop, 27 Sussex Place, Regent's Park, London NW1 4RG; Telephone: +44 020 7772 6276; Fax, +44 020 7772 5991; e-mail: bookshop@rcog.org.uk. A listing and order form are available from the RCOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Guidance for the development of RCOG green-top guidelines. Clinical Governance Advice No 1. 2000 Jan. Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.

- Searching for evidence. Clinical Governance Advice No 3. 2001 Oct. Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.

PATIENT RESOURCES

The following is available:

- HIV in pregnancy - information for you. Royal College of Obstetricians and Gynaecologists, 2005 Feb. 12 p. Electronic copies: Available from the Royal College of Obstetricians and Gynaecologists Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455, ref: 23809. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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